UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,231	11/17/2000	Susan R. Webb	TSRI 536.1Div1	7187

7590 03/26/2002

THE SCRIPPS RESEARCH INSTITUTE
10550 North Torrey Pines Road
Mail Drop: TPC-8
La Jolla, CA 92037

EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	6

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/715,231	Webb et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communicati n app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 9, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *33-60, 85-91, 100-103, and 114-140* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *33-60, 85-91, 100-103, and 114-140* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 33-60, drawn to a synthetic antigen presenting matrix for activating CD4+ T cells comprising a) a support, b) an extracellular portion of a MHC Class II heterodimer and c) an extracellular portion of at least one accessory molecule, classified in class 530, subclasses 328 and 350,

II. Claims 85-91 and 114-136, drawn to a method of producing a synthetic antigen matrix comprising A) providing an extracellular portion of a recombinant MHC Class II heterodimer, b) providing an extracellular portion of at least one recombinant accessory molecule, and c) linking the MHC Class II heterodimer and accessory molecule to a support, classified in class 530, subclasses 328 and 350,

III. Claims 100-103, drawn to a method for activating CD4+ T cells in vitro, comprising providing the matrix of claim 33, loading the MHC Class II heterodimer with a peptide and contacting the peptide-loaded cell matrix with the CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, classified in class 424, subclass 193.1, or

IV. Claims 137-140, drawn to a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting matrix according to claim 33 with a peptide library in vitro, contacting the peptide loaded MHC Class II heterodimer with CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, classified in class 424, subclass 193.1, and class 436, subclass 536.

The inventions are distinct, each from the other because:

2. Groups II-IV are drawn to distinct methods because the endpoints of Group II and the endpoint of Groups III/IV are different. Though the endpoints of Groups III and IV are the same, they differ in their process steps, the former comprising loading the MHC Class II heterodimer with one peptide, the latter comprising loading the MHC Class II heterodimer with a peptide library in vitro. Therefore, Groups II-IV are patentably distinct, each from the other.

3. Groups I and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the synthetic antigen presenting matrix, can be used in a method for screening analogs of peptide epitopes, as well as in a method for activating CD4+ T cells in vitro.

4. Groups II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the the synthetic antigen presenting matrix, can be made by immunoprecipitating lysed antigen presenting cells with an antibody coupled to Protein A beads.

5. A) If Group I is elected, the applicant is further required under 35 U.S.C. 121:

I) to elect a synthetic antigen presenting matrix comprising a **specific support**, such as a cell fragment as recited in claim 34, or a cell as recited in claim 35, or a liposome as recited in claim 37, or a solid surface as recited in claim 38,

II) to elect a synthetic antigen presenting matrix comprising a **specific combination** of **specific accessory molecule(s)**, such as a costimulatory molecule as recited in claim 44, or an adhesion molecule as recited in claim 46, or a survival molecule as recited in claim 48,

A) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 45,

B) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 47,

C) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 49,

B) If Group II is elected, the applicant is further required:

I) to elect a method of producing a synthetic antigen presenting matrix comprising a **specific support**, such as a cell fragment as recited in claim 114, or a cell as recited in claim 115, or a liposome as recited in claim 119, or a solid surface as recited in claim 120,

A) If a cell is elected, then applicant is required to elect a specific cell, such as an insect cell as recited in claim 116,

I) if an insect cell is elected, applicant is further required to elect a specific insect cell such as drosophila as recited in claim 117,

ii) to elect a method of producing a synthetic antigen presenting matrix comprising a **specific combination** of **specific accessory molecule(s)**, such as a costimulatory molecule as recited in claim 86, or an adhesion molecule as recited in claim 88, or a survival molecule as recited in claim 90,

A) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim

87,

B) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 89,

C) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 91,

C) A) If Group III or IV is elected, the applicant is further required under 35 U.S.C. 121:

I) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a **specific support**, such as a cell fragment as recited in claim 34, or a cell as recited in claim 35, or a liposome as recited in claim 37, or a solid surface as recited in claim 38,

II) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a **specific combination** of **specific accessory molecule(s)**, such as a costimulatory molecule as recited in claim 44, or an adhesion molecule as recited in claim 46, or a survival molecule as recited in claim 48,

A) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 45,

B) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 47,

C) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 49,

III) to elect a method for activating CD4+ T cells in vitro comprising a synthetic antigen presenting matrix comprising a **specific peptide** if Group III is elected, **or** elect a **specific peptide library** if Group IV is elected.

6. Claims 33-60, 85-91, 100-103, and 114-140 are generic, in at least one aspect.

7. The species are distinct each from the other for the following reasons:

A) Specific supports, each encompass compositions and physical structures with unique properties.

B) Specific accessory molecules differ with respect to their biophysical structure and function.

C) Specific peptides differ with respect to their amino acid sequences and their biophysical structure and function.

D) Peptide libraries differ with respect to the amino acid sequences and/or length of the encompassed peptides

8. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable.

The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. a Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at

paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 25, 2002

Amy DeCloux 3-25-02